I guess I should also take a crack at the new mod(e)rna data in the NEJM

And the confirmations just keep coming...

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Please head to the latest New England Journal of Medicine (NEJM) article entitled: "Evaluation of mRNA-1273 Vaccine in Children 6 Months to 5 Years of Age" published on October 21,2022. It's a late assessment of the 'unknown' "safety, reactogenicity, immunogenicity, and efficacy of the mRNA-1273 coronavirus disease 2019 (Covid-19) vaccine in young children". It's not even funny how they are publishing this assessment of unknown safety factors 4 months AFTER they starting injecting children ages 6 months to 5 years of age. I have been bitching about this for a long time now.

This is just another stunning example of how Eric Rubin really wasn't kidding around when he publicly announced that 'we won't know how safe these products are until we start putting them into babies (people)". Maybe this *is* just the way it goes now, eh? Funny how this guy is the Editor-in-Chief of this very journal.

So the following is just some of what they buried in the Supplementary Appendix. I literally just glanced at it and found a few things that made me wince.

The first thing I want to point out is a strange mis-use of the word 'place-bo' in the Trial Vaccine description on page 11. At first glance I thought, well this must be the result of the word 'placebo' previously having been spliced due to word spacing/processing - say, from having been sourced from another document.

Trial Vaccine

The mRNA-1273 vaccine is a lipid nanoparticle dispersion of an mRNA that encodes the prefusion stabilized S protein of SARS CoV-2 formulated and composed of 4 lipids as previously described.[2] The mRNA-1273 injection is provided as a sterile liquid at a concentration of 0.2 mg/mL in 20 mM Tris buffer containing 87 mg/mL sucrose and 4.3 mM sodium acetate at pH 7.5, consisting of 25-µg, 50-µg or 100-µg doses of mRNA1273, or place-bo (normal saline) per assigned treatment diluted with normal saline to a final injection volume of 0.5 mL. Each participant is to receive 2 intramuscular injections of study vaccine approximately 28 days apart (days 1 and 29) for parts 1 and 2, administered into the deltoid muscle or anterolateral thigh (per investigator's discretion). At each visit after study vaccine is administered, participants are monitored for a minimum of 30 minutes, and assessed for body temperature measurements (oral preferred for participants >4 years of age, tympanic preferred for participants ≤4 years of age, but other methods acceptable in context of Covid-19 precautions) and monitoring for local or systemic reactions. The study sites are appropriately

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Figure 1: Place-bo? https://www.nejm.org/doi/suppl/10.1056/NEJMoa2209367/suppl_file/nejmoa2209367_appendix.pdf. Page 11.

But, if this was the case, why is this not recurring in other words in the hefty paragraph? You might think I am being litigious here, and I am, because one thing that I have learned from all of this COVID 2-years to fatten the pockets of billionaires nonsense, is the ***might of the word***, especially in legal documents. Since the word 'placebo' is not spelled correctly, then it could be argued that what they are referring to is not, in fact, a placebo - by anyone's definition. Now they do apply a descriptor in brackets (normal saline) so I am not going to make any claims here, but I did find the mis-spelling of the word placebo, odd. I find it odd because of all the shenanigans with placebos - and lack thereof - in the contexts of vaccine trials. And in the contexts of the Pfizer and Moderna data that I have been looking at for 2 years now, I have my doubts that they are using saline as a placebo, or that their placebo is inert. I think they use empty LNPs. And the LNPs are dangerous.

The second thing I want to point out is what both Alex Berenson and El Gato Malo have pointed out in their excellent assessments of this NEJM article's Supplementary Appendix, and that is the *new* (they use the word 'new' even though making sure to point out that this baby was 'pre-disposed') onset of Type-I diabetes in a 1-year old within 37 days of Dose 2. This is considered to be a 'Serious' adverse event. Now, you might look at this and say, well Jess, it's only 0.1% of the babies that suffered a Serious UNSOLICITED (this basically means unexpected) adverse event in the context of the mRNA-1273 shot. That's nothing to worry about, right?

And I would say, that's 1/1,000 babies. You wanna roll those dice?

By the way, you might also remember me previously writing on the fact that in their (Moderna and Pfizer) assessments of adverse event data, they use the words 'Severe' and 'Serious' to describe 'different' things. I believe they do this to make the data look sparser than it actually is. Let's just refer to a spontaneous abortion using 20 different MedDRA codes! That'll solve the problem of big numbers!

Notice the number and percentage of Severe unsolicited AEs related to study 'vaccination': 14 reports which comprises 0.8% of the babies they studied. Just wanted to point that out. It doesn't change the over-all percentage, but remember, these are babies and even 1 matters in the context of harm induced by a medical intervention.

Table S26. Summary of Unsolicited Adverse Events After Any Injection Throughout the Study

n (%)	2-5 years Placebo N=1007	2-5 years mRNA-1273 25 µg N=3031	6-23 months Placebo N=589	6-23 months mRNA-1273 25 µg N=1911
Unsolicited AEs regardless of relationship to study vaccination				
All	512 (50.8)	1561 (51.5)	348 (59.1)	1022 (58.0)
Serious	2 (0.2)	9 (0.3)	1 (0.2)	15 (0.9)
Fatal	0	0	0	0
Medically attended	344 (34.2)	1002 (33.1)	242 (41.1)	678 (38.5)
Leading to discontinuation from study vaccine	0	0	1 (0.2)	1 (<0.1)
Leading to discontinuation from study	0	0	1 (0.2)	0
Severe	11 (1.1)	25 (0.8)	5 (0.8)	26 (1.5)
Non-serious	512 (50.8)	1558 (51.4)	348 (59.1)	1019 (57.9)
Severe	10 (1.0)	23 (0.8)	4 (0.7)	18 (1.0)
Special interest (AESI)	1 (<0.1)	5 (0.2)	1 (0.2)	4 (0.2)
MIS-C	0	0	0	0
Other	1 (<0.1)	5 (0.2)	1 (0.2)	4 (0.2)
Unsolicited AEs related to study vaccination				
All	82 (8.1)	290 (9.6)	72 (12.2)	298 (16.9)
Serious	0	0	0	2 (0.1)*
Fatal	0	0	0	0
Medically-attended	3 (0.3)	31 (1.0)	5 (0.8)	26 (1.5)
Leading to discontinuation from study vaccine	0	0	0	1 (<0.1)
Leading to discontinuation from study	0	0	0	0
Severe	8 (0.8)	19 (0.6)	3 (0.5)	14 (0.8)
Non-serious	82 (8.1)	290 (9.6)	72 (12.2)	298 (16.9)
Severe	8 (0.8)	19 (0.6)	3 (0.5)	13 (0.7)
Special interest (AESI)	1 (<0.1)	2 (<0.1)	0	2 (0.1)
MIS-C	0	0	0	0
Other	1 (<0.1)	2 (<0.1)	0	2 (0.1)

AE, adverse event; AESI, adverse event of special interest; MIS-C, multisystem inflammatory syndrome in children. An AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. Solicited adverse reactions with toxicity grade = 0 that lasted beyond day 7 or started after day 7 are not included in this table. *Two participants reported SAEs considered related to study vaccination through the study including 1 SAE of pyrexia and febrile convulsion (SAE reported within 28 days, Tables S21 and S24); the other SAE considered related was new-onset Type 1 diabetes mellitus and diabetic ketoacidosis in a 1-year-old female reported 37 days post dose 2. This child has a significant family history of diabetes mellitus and a recent URI. Assessed as related, the Investigator also noted that the event is "more likely caused by a genetic predisposition to pre-diabetes and viral upper respiratory tract infection that occurred prior to second dose of study vaccine. Data cut-off date: February 21, 2022.

Figure 2: Severe and Serious AEs unsolicited and related to injections in babies ages 6-23 months. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2209367/suppl_file/nejmoa2209367_appendix.pdf. Page 62.

The third thing I want to point out is on page 45 in the Supplementary Appendix. What caught my eye here are the percentages of babies and children who reported **medical intervention requirements** in the cases of unsolicited AEs that occurred within days (<28 days) of any injection. In the case of the babies ages 6-23 months, 30% reported medical attendance in the context of their AE and I might add here, that the dose used here was low (25 ug) and, **they only looked at 150 babies**. Napkin math time. If we injected 100,000 babies ages 6-23 months with this experimental mRNA-1273 gene therapy, according to this data, **30,000** would need medical attention. Think about that. And not just medically. Think, economically.

Table S11. Summary of Unsolicited Adverse Events <28 Days After Any Injection in Children 2–5 Years and 6–23 Months in Part 1 Safety Set

Unsolicited Adverse events n (%)	2-5 years mRNA-1273 50 µg N=69	2-5 years mRNA-1273 25 µg N=155	6-23 months mRNA-1273 25 µg N=150
Unsolicited AEs regardless of relationship to study vaccination			
All	16 (23.2)	56 (36.1)	80 (53.3)
Serious	0	0	2 (1.3)
Fatal	0	0	0
Medically attended	5 (7.2)	32 (20.6)	45 (30.0)
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from study	0	0	0
Severe	0	4 (2.6)	4 (2.7)
Non-serious	16 (23.2)	56 (36.1)	80 (53.3)
Severe	0	4 (2.6)	2 (1.3)
Special interest (AESI)	0	0	1 (0.7)
MIS-C	0	0	0
Other	0	0	1 (0.7)*
Unsolicited AEs related to study vaccination			
All	5 (7.2)	17 (11.0)	23 (15.3)
Serious	0	0	0
Fatal	0	0	0
Medically attended	0	3 (1.9)	4 (2.7)
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from study	0	0	0
Severe	0	3 (1.9)	2 (1.3)
Non-serious	5 (7.2)	17 (11.0)	23 (15.3)
Severe	0	3 (1.9)	2 (1.3)
Special interest (AESI)	0	0	0
MIS-C	0	0	0
Other	0	0	0

AE, adverse event; AESI, adverse event of special interest; MIS-C, multisystem inflammatory syndrome in children. AE is defined as any event not present before exposure to study vaccination or any event already present that worsened in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. Solicited adverse reactions with toxicity grade = 0 that lasted beyond day 7 or started after day 7 are not included in this table. *1-year-old male in mRNA-1273 group experienced grade 3 AESI (also an SAE for overnight hospitalization) of febrile convulsion 10 days after injection 2 that resolved the same day considered by investigator to not be related to study vaccination with occurrence of maculo-papular rash onset 2 days before the event of febrile seizure (8 days post-infection 2). After the analysis cutoff date, a 3-year-old participant was diagnosed with MIS-C that started 113 days after placebo injection 2, considered not related by the investigator. The participant had a grade 1 asymptomatic SARS-CoV-2 infection 37 days prior to the onset of symptoms. Five days after onset of MIS-C symptoms, the child was hospitalized then discharged after 4 days with a diagnosis of MIS-C and was recovering. Data cut-off date: February 21, 2022.

Figure 3: Medically attended Unsolicited AEs related to study 'vaccination'. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2209367/suppl_file/nejmoa2209367_appendix.pdf. Page 45.

By the way, you'll notice in the paragraph at the bottom that a 1-year-old boy suffered a febrile convulsion 10 days after injection. Sound familiar from my previous writings? Does a seizure induced by a high fever in a baby too young to hold up their head sound like something you want to experience, or have your baby experience? And 0.7% of the time in the context of an injection that your baby doesn't need? They called this febrile seizure experience in this baby: 'Other' and claimed that it resolved the same day. Ok.

And the last thing I would like to point out (it is NOT the final thing) is on page 59. When sorting by System Organ Class (broader classification), their data show that almost half of the babies had reports of unsolicited adverse events: **65.5%** not 49.1% as they report! They actually divided the number of unsolicited AEs by the total of the Placebo and mRNA arms ***for some reason*** (1153/2350*100=49.1%). Of these, 1.2% reported a Severe adverse event however, this is the percentage calculated from the total. If you calculate the percentage of 'Any' adverse events reports considered 'Severe', the percentage goes up to 1.8%. Not a huge jump, but it matters.

Table S23. Summary of Unsolicited and Severe Adverse Events Reported ≤28 Days in Children 6–23 Months After Any Injection by MedDRA Primary System Organ Class and Preferred Term in Part 2 Safety Set

System Organ Class Preferred Term n (%)	Placebo N=589 Any	Placebo N=589 Severe	mRNA-1273 25 µg (N=1761) Any	mRNA-1273 25 µg (N=1761) Severe
Number of participants reporting unsolicited adverse events	284 (48.2)	4 (0.7)	1153 (49.1)	21 (1.2)
Number of unsolicited adverse events	572	6	1711	25
Infections and infestations	183 (31.1)	1 (0.2)	526 (29.9)	7 (0.4)
Respiratory tract infection viral	2 (0.3)	1 (0.2)	3 (0.2)	1 (<0.1)
Bronchiolitis	2 (0.3)	0	7 (0.4)	1 (<0.1)
Gastroenteritis viral	3 (0.5)	0	12 (0.7)	1 (<0.1)
Hand-foot-and-mouth disease	526 (29.9)	1 (0.2)	27 (1.5)	0
Mastoiditis	0	0	1 (<0.1)	1 (<0.1)
Pneumonia	0	0	3 (0.2)	1 (<0.1)
Respiratory syncytial virus infection	3 (0.5)	0	3 (0.5)	1 (<0.1)
Rhinovirus infection	0	0	9 (0.5)	1 (<0.1)
Immune system disorders	8 (1.4)	0	8 (0.5)	1 (<0.1)
Food allergy	4 (0.7)	0	2 (0.1)	1 (<0.1)
Metabolism and nutrition disorders	26 (4.4)	1 (0.2)	71 (4.0)	4 (0.2)
Decreased appetite	26 (4.4)	1 (0.2)	68 (3.9)	3 (0.2)
Electrolyte imbalance	0	0	1 (<0.1)	1 (<0.1)
Psychiatric disorders	48 (8.1)	1 (0.2)	152 (8.6)	8 (0.5)
Irritability	47 (8.0)	1 (0.2)	151 (8.6)	8 (0.5)
Nervous system disorders	15 (2.5)	0	38 (2.2)	2 (0.1)
Febrile convulsion	0	0	2 (0.1)	2 (0.1)
Respiratory, thoracic and mediastinal disorders	46 (7.8)	0	143 (8.1)	0
Cough	21 (3.6)	0	74 (4.2)	0
Wheezing	0	0	1 (<0.1)	0
Skin and subcutaneous tissue disorders	21 (3.6)	0	52 (3.0)	1 (<0.1)
Urticaria	5 (0.8)	0	7 (0.4)	1 (<0.1)
General disorders and administration site conditions	37 (6.3)	2 (0.3)	147 (8.3)	1 (<0.1)
Pyrexia	31 (5.3)	2 (0.3)	31 (5.3)	1 (<0.1)
Injury, poisoning and procedural complications	10 (1.7)	0	30 (1.7)	1 (<0.1)
Radial head dislocation	1 (0.2)	0	3 (0.2)	1 (<0.1)

Covid-19, coronavirus disease 2019; MedDRA, Medical Dictionary for Regulatory Activities. Percentages are based on the number of safety participants. MedDRA version 23.0. Data cut-off date: February 21, 2022.

65.5%
89.3%

Figure 4: Number of babies with Unsolicited AEs within 28 days of injection. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2209367/suppl_file/nejmoa2209367_appendix.pdf. Page 59.

And by the way, once again, why did half of the babies in the Placebo arm experience and report unsolicited AEs of which 0.7% were Severe? Kind of makes you wonder about my first point, eh?

And one more important thing, notice the Hand-foot-and-mouth disease rate in the Placebo 'Any' arm? They might have miscalculated the rate or incorrectly written in the absolute number of reports. I am not sure. If the former, then this means that 89.3% of the babies ages 6-23 months in the Placebo arm experienced and reported Hand-foot-and-mouth disease. Really? I find this suspect. If I was a betting woman, I would go with the latter explanation as the correct one and point out that, hey, this is AN INCREDIBLY IMPORTANT STUDY AND ANALYSIS. MAYBE DOUBLE CHECK YOUR WORK. You're welcome.

Even if the percentage is correct (meaning 176 babies got the hand and footy rot), this is still a very high rate, especially in the context of Placebo, and would require explanation, in my opinion.

And by the way, a reader told me they are going to start introducing FMD mRNA injections to livestock in NSW. It appears to be true. Read about it here.